IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
Eastern Division

THOMAS W. DURKIN, as Special Administrator of the Estate of MARY V. DURKIN, Plaintiff, v. BAYER CORPORATION, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE LLC, and BAYER A.G., Defendants.	 Civil Action No. _____ JURY TRIAL DEMANDED

ANSWER AND ADDITIONAL DEFENSES OF BAYER CORPORATION

Defendant Bayer Corporation, for its Answer to Plaintiff's Complaint (the "Complaint"), states as follows:

1. THOMAS W. DURKIN, is a resident of the State of Illinois and is the Special Administrator of the Estate of MARY V. DURKIN, deceased, having been duly appointed by the Circuit Court of Cook County, Illinois, on November 20, 2007.

1. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint.

2 Plaintiff's decedent, MARY V. DURKIN, a resident of the State of Illinois, died on November 27, 2003.

2. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint.

3. Defendant BAYER CORPORATION is a corporation formed in the State of Indiana with its principal place of business located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205. It is a wholly owned subsidiary of Defendant Bayer A.G. At all times material to this lawsuit, Bayer was engaged in the

business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce and the State of Illinois, either directly or indirectly, the pharmaceutical Trasylol, also known as Aprotinin. BAYER CORPORATION may be served by delivering a copy of this complaint and summons to its agent for service in Illinois, Illinois Corporation Service C., 801 Adlai Stevenson Drive, Springfield, IL 62703.

3. Bayer Corporation admits that it is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205; that Bayer Corporation is a wholly owned subsidiary of Bayer AG; and that Trasylol® is the proprietary name for aprotinin injection. Bayer Corporation admits that its agent for service of process in Illinois is Illinois Corporation Service Company, located at 801 Adlai Stevenson Drive, Springfield, IL 62703. Bayer Corporation is without knowledge or information sufficient to form a belief as to the time frame to which the allegations in the third sentence of paragraph 3 of the Complaint refer, but denies that it was promoting, marketing, distributing, testing, or selling Trasylol® at the time of the procedure alleged in the Complaint, and denies that it has developed, manufactured, or licensed Trasylol®. Because of the vagueness of the allegation in paragraph 3 that Bayer Corporation was "warranting" Trasylol®, Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of that allegation. Bayer Corporation denies the remaining allegations in paragraph 3 of the Complaint.

4. *Defendant BAYER PHARMACEUTICALS CORPORATION is a wholly owned subsidiary of Defendant Bayer Corporation, incorporated in the state of Delaware, with its principal place of business located at 400 Morgan Lane, West Haven, Connecticut 06516. At all times material to this lawsuit, Bayer Pharmaceuticals Corporation was engaged in the business of developing, manufacturing , licensing, promoting, marketing ,distributing, testing, warranting and/or selling in interstate commerce and the State of Connecticut, either directly or indirectly, the pharmaceutical Trasylol, also known as Aprotinin. BAYER PHARMACEUTICALS CORPORATION may be served by delivering a copy of this complaint and summons to it agent for service in Illinois, Illinois Corporation Service C., 801 Adlai Stevenson Drive, Springfield, IL 62703. On information and belief, this Defendant conducts business under the name BAYER HEALTHCARE PHARMACEUTICALS.*

4. Bayer Corporation admits that Bayer Pharmaceuticals Corporation is a Delaware corporation and a wholly owned subsidiary of Bayer Corporation with its principal place of business at 400 Morgan Lane, West Haven, Connecticut 06515; that Trasylol® is the proprietary name for aprotinin injection; and that Bayer Pharmaceuticals Corporation's agent for service of process in Illinois is Illinois Corporation Service Company, located at 801 Adlai Stevenson Drive, Springfield, IL 62703. Bayer Corporation is without knowledge or information sufficient to form a belief as to the time frame to which the allegations in the second sentence of paragraph 4 of the Complaint refer, but admits that at the time of the procedure alleged in the Complaint Bayer Pharmaceuticals Corporation was promoting, marketing, distributing, testing, and/or selling Trasylol® in interstate commerce in the United States, including in Connecticut. Because of the vagueness of the allegation that Bayer Pharmaceuticals Corporation was "warranting" Trasylol®, Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of that allegation in paragraph 4 of the Complaint. Bayer Corporation denies the remaining allegations in paragraph 4 of the Complaint.

5. Defendant BAYER HEALTHCARE LLC is Limited Liability Company whose sole member is Defendant Bayer Corporation. On information and belief, Bayer Healthcare LLC is a citizen of both Indiana and Pennsylvania. At all times material to this lawsuit, Bayer Healthcare LLC was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce and the State of Illinois, either directly or indirectly, the pharmaceutical Trasylol, also known as Aprotinin. BAYER HEALTHCARE LLC may be serviced by delivering a copy of this complaint and summons to its agent for service in Illinois, Illinois Corporation Service C., 801 Adlai Stevenson Drive, Springfield, IL 62703. On information and belief, this Defendant conducts business under the name BAYER HEALTHCARE PHARMACEUTICALS.

5. Bayer Corporation admits that Bayer HealthCare LLC is a limited liability company whose sole member is Bayer Corporation; that Bayer HealthCare LLC is considered a citizen of both Indiana and Pennsylvania for purposes of 28 U.S.C. § 1332; that Trasylol® is the

proprietary name for aprotinin injection; and that Bayer HealthCare LLC's agent for service of process in Illinois is Illinois Corporation Service Company, located at 801 Adlai Stevenson Drive, Springfield, IL 62703. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 5 of the Complaint.

> *6. Defendant BAYER AG, a global diversified chemical company, is a German corporation, with its principal place of business in Leverkusen, Germany. At all times relevant herein, Bayer AG was in the business of designing, testing, manufacturing, distributing and promoting certain pharmaceutical products, including Trasylol. Additionally, at all times relevant hereto, Bayer Corporation and Bayer A.G. shared many of the same officers and directors. Service on Bayer A.G. is being performed pursuant to the Hague Convention on service abroad. Hereinafter Bayer Corporation, Bayer Healthcare and Bayer AG may be collectively referred to as the "Defendants."*

6. Bayer Corporation admits that Bayer AG is a German corporation with its headquarters in Leverkusen, Germany. Bayer Corporation is without knowledge or information sufficient to form a belief as to the time frame to which the allegations in paragraph 6 of the Complaint refer, but denies that Bayer AG was designing, testing, manufacturing, distributing, or promoting prescription pharmaceuticals, including Trasylol®, at the time of the procedure alleged in the Complaint. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth sentence of paragraph 6 of the Complaint. Although Bayer Corporation admits that the Complaint contains allegations referring to Bayer Corporation and other entities collectively as "Defendants," "Defendant," and/or "Bayer," Bayer Corporation is not answering the Complaint on behalf of any entity other than Bayer Corporation and is not answering allegations that are directed to any entity other than Bayer Corporation, and accordingly denies the allegations in the final sentence in paragraph 6 of the Complaint. Bayer Corporation denies the remaining allegations in paragraph 6 of the Complaint.

7. *Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:*

7. Bayer Corporation incorporates by reference its responses to each and every paragraph of the Complaint.

8. Trasylol (also known as Aprotinin injection) is a naturally occurring proteolytic enzyme inhibitor obtained from bovine lung. Aprotinin consists of 58 amino acid residues. It is a single chain polypeptide, consisting of 6512 daltons and is cross-linked by three disulfide bridges.

8. Bayer Corporation admits that Trasylol® is the proprietary name for aprotinin injection, that Trasylol® is a natural protease inhibitor obtained from bovine lung, that Trasylol® consists of 58 amino acid residues that are arranged in a single polypeptide chain, cross-linked by three disulfide bridges, and that it has a molecular weight of 6512 daltons. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 8 of the Complaint.

9. The reactive bond site for Aprotinin is lysine –15 – alanine –16 and it forms reversible stoichiometric complexes.

9. Bayer Corporation admits that the active center of the aprotinin molecule is located on the lysine 15 and alanine 16 amino acid residues and that aprotinin forms reversible stoichiometric enzyme-inhibitor complexes. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 9 of the Complaint.

10. Aprotinin reacts with the serine site of the enzyme.

10. Because of the vagueness of the allegation, Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegation in paragraph 10 of the Complaint.

11. Aprotinin was discovered in the 1930s when Kraut et al isolated a kallikrein inhibitor from Bovine lung.

11. Bayer Corporation admits that, in or around 1930, Dr. Kraut and others isolated a kallikrein inhibitor from bovine lung. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 11 of the Complaint.

12. Aprotinin was launched as Trasylol in Germany in 1959.

12. Bayer Corporation admits that aprotinin was first marketed as "Trasylol" in Germany in 1959 for treatment of pancreatitis. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 12 of the Complaint.

13. Trasylol was approved by the FDA in 1993 and is used to control bleeding in open-heart surgeries. It is supplied as a clear, colorless, sterile isotonic solution for intravenous administration.

13. Bayer Corporation admits that the United States Food and Drug Administration ("FDA") approved the sale and distribution of Trasylol® in the United States on December 28, 1993, and that Trasylol® is supplied as a clear, colorless, sterile isotonic solution for intravenous administration. Bayer Corporation admits that, at the time of the procedure alleged in the Complaint, Trasylol® was indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 13 of the Complaint.

14. Trasylol is indicated for prophylactic use to reduce peri-operative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of open-heart surgical procedures.

14. Bayer Corporation admits that at the time of the procedure alleged in the Complaint, Trasylol® was indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of

coronary artery bypass graft surgery. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 14 of the Complaint.

15. Trasylol is a broad spectrum protease inhibitor, which modulates the systemic inflammatory response associated with cardiopulmonary bypass surgery. The effects of Trasylol use in cardiopulmonary bypass surgery involve a reduction in inflammatory response, which translates into a decreased need for blood transfusions.

15. Bayer Corporation admits the allegations in paragraph 15 of the Complaint.

16. The following is the warning carried by Trasylol prior to the FDA Advisory Board Committee Meeting:

Anaphylactic or anaphylactoid reactions are possible when Trasylol is administered. Hypersensitivity reactions are rare in patients with no prior exposure to Aprotinin. The risk of anaphylaxis is increased in patients who are re-exposed to Aprotinin-containing products. The benefit of Trasylol to patients undergoing primary CABG surgery should be weighed against the risk of anaphylaxis should a second exposure be required."

16. Bayer Corporation admits that, at the time of the procedure alleged in the Complaint, the language quoted in paragraph 16 of the Complaint was contained in labeling for Trasylol®. Because of the vagueness of the time frame of the allegations in paragraph 16 of the Complaint, Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 16 of the Complaint.

17 Trasylol inhibits pro-inflammatory cytokine release and maintains glycoprotein homeostasis.

17. Bayer Corporation admits the allegations in paragraph 17 of the Complaint.

18. According to Bayer, since its approval, an estimated 4.3 million patients have been given Trasylol®.

18. Bayer Corporation admits that from January 1, 1985, through March 31, 2006, there had been an estimated cumulative 4.38 million patient exposures worldwide to Trasylol®.

Bayer Corporation denies the remaining or inconsistent allegations in paragraph 18 of the Complaint.

19. Bayer estimated that Trasylol generated about $293 million in sales in 2005 alone, making it the company's 11th largest selling drug.

19. Bayer Corporation admits that it was reported in the 2005 Annual Report of Bayer AG that in 2005 Trasylol® generated sales of €230 million and was listed as eleventh among the "Best-Selling Bayer HealthCare Products." Bayer Corporation denies the remaining or inconsistent allegations in paragraph 19 of the Complaint.

20. In late 2005, Bayer forecast that Trasylol would someday generate upwards of $600 million annually.

20. Bayer Corporation admits that in late 2005 it was estimated that the sales potential of Trasylol® could exceed €500 million. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 20 of the Complaint.

21. On November 25, 2007, under increasing government pressure, Bayer AG said that it had halted worldwide sales of Trasylol after a Canadian clinic study found the drug could be linked to a higher risk of death than other drugs.

21. Bayer Corporation admits that, on November 5, 2007, worldwide marketing of Trasylol® was temporarily suspended until final results from a Canadian trial, known as the BART trial, could be received, compiled, and evaluated. This action followed information that the BART study had been halted after a planned periodic data analysis indicated reduced bleeding but also an increase in all-cause mortality (that almost reached conventional statistical significance for 30-day mortality) for patients receiving Trasylol® compared to patients who received either aminocaproic acid or tranexamic acid. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 21 of the Complaint. *22. The Food and Drug Administration asked the company to stop selling the drug, used to prevent excessive bleeding during heart bypass surgery, pending detailed review of preliminary results from the Canadian study.*

22. Bayer Corporation admits that at the time of the procedure alleged in the Complaint Trasylol® was indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of

coronary artery bypass graft surgery. Bayer Corporation further admits that on November 5, 2007, FDA announced that, at the agency's request, Bayer Pharmaceuticals Corporation had agreed to a marketing suspension of Trasylol® pending detailed review of preliminary results from the Canadian BART trial. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 22 of the Complaint.

23. On January 26, 2006, The New England Journal of Medicine (NEJM) published an article by Mangano et al. reporting an association of Trasylol with, among other things, serious renal toxicity in patients undergoing coronary artery bypass grafting surgery. This study was an observational study of patients who received either Trasylol, one of two alternative drugs intended to decrease peri-operative bleeding (aminocaproic acid or tranexamic acid), or no specific drug treatment.

23. Bayer Corporation admits that an article authored by Mangano et al. was published in *The New England Journal of Medicine* on or about January 26, 2006. That article speaks for itself, and Bayer Corporation denies the allegations in paragraph 23 of the Complaint to the extent they are inconsistent with the contents of the article. Bayer Corporation denies the remaining allegations in paragraph 23 of the Complaint.

24. The FDA evaluated this study, along with other studies in the literature, and reports submitted to the FDA through the MedWatch program, to determine if labeling changes or other actions were warranted.

24. Bayer Corporation admits that the FDA receives and reviews various sources of information regarding approved pharmaceuticals, including studies in the medical and scientific literature and reports submitted through the MedWatch program, and evaluates whether labeling changes and other actions are warranted with regard to prescription drugs. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 24 of the Complaint.

25. While the FDA was continuing its evaluation it provided the following recommendations to healthcare providers and patients:

Physicians who use Trasylol should carefully monitor patients for the occurrence of toxicity, particularly to the kidneys, heart, or central nervous system and promptly report adverse event information to Bayer, the drug manufacturer, or to the FDA MedWatch program, as described at the end of this advisory.

Physicians should consider limiting Trasylol use to those situations where the clinical benefit of reduced blood loss is essential to medical management of the patient and outweighs the potential risks.

25. Bayer Corporation admits that the FDA issued a Public Health Advisory on or about February 8, 2006, portions of which are quoted in the indented portions of paragraph 25 of the Complaint. Bayer Corporation denies the allegations in paragraph 25 of the Complaint to the extent they are inconsistent with the contents of that Advisory. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 25 of the Complaint, including the time frame during which the FDA was "continuing its evaluation."

26. The FDA Advisory Board Committee convened on September 21, 2006 to discuss its findings regarding the safety of Trasylol and determine whether the warning on Trasylol needed to be changed.

26. Bayer Corporation admits that the FDA convened a public meeting of the Cardiovascular and Renal Drugs Advisory Committee on September 21, 2006, to discuss Trasylol®. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 26 of the Complaint.

27. After reviewing what it considered to be all of the available data on the safety of Trasylol, the 19-member advisory panel recommended to the FDA that Defendant Bayer did not need to strengthen a warning to doctors about the drug.

27. Bayer Corporation denies the allegations in paragraph 27 of the Complaint.

28. Just days later, the FDA was contacted by Alexander Walker, a professor at Harvard's School of Public Health, about a 67,000-patient study he assisted in conducting at Bayer's request.

28. Bayer Corporation admits that at the request of Bayer HealthCare AG Dr. Alexander Walker of i3 Drug Safety was performing an observational study of data drawn from a commercial database involving patients who underwent coronary artery bypass graft surgery. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 28 of the Complaint.

29. Bayer knew of this study and data and failed to disclose this data to the FDA at the September 21 Advisory Board Committee meeting. This new data from the Harvard School of Public Health study (hereinafter the "Walker Study") confirmed that Trasylol increased the risk of renal failure, among other things.

29. Bayer Corporation admits that it knew that i3 Drug Safety's observational study of data drawn from a commercial database was ongoing, but denies that it knew that data or results from i3 Drug Safety's observational study were available prior to the September 21, 2006, Advisory Committee meeting and further denies Plaintiff's characterization of such preliminary data. Bayer Corporation denies the remaining allegations in paragraph 29 of the Complaint.

30. The Walker study, conducted at Bayer's request, examined 67,000 hospital records of patients undergoing bypass surgery. The study suggests that the patients who received Trasylol were at an increased risk for death, kidney failure, congestive heart failure, and stroke.

30. Bayer Corporation admits that at the request of Bayer HealthCare AG i3 Drug Safety was performing an observational study of data drawn from a commercial database involving patients who underwent coronary artery bypass graft surgery. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 30 of the Complaint.

31. On December 15, 2006, the FDA sent an Alert to healthcare professionals advising of a change in the product label for Trasylol

The new labeling for Trasylol (December 2006) has a more focused indication for use, a new Warning about renal dysfunction, a revised Warning about anaphylactic reactions, and a new Contraindication. Trasylol is now indicated only for prophylactic use to reduce peri-operative blood loss and the need for blood transfusion in patients who are at an increased risk for blood loss

and blood transfusion undergoing cardiopulmonary bypass in the course of coronary artery bypass grafting (CABG) surgery. Trasylol should be administered only in the operative setting where cardiopulmonary bypass can be started quickly. Trasylol should not be administered to any patient with a known or suspected exposure to Aprotinin within the past 12 months.

FDA is evaluating additional recently submitted epidemiological safety study data (discussed below), in the context of all other safety and efficacy information available on Aprotinin. This review may result in other actions, including additional changes to the full prescribing information (product labeling).

31. Bayer Corporation admits that on or about December 15, 2006, the FDA issued an "FDA Alert," portions of which are quoted in the indented portions of paragraph 31 of the Complaint. Bayer Corporation denies the allegations in paragraph 31 of the Complaint to the extent they are inconsistent with the contents of that Alert.

32. Moreover, on or about December 2006, the Defendants revised the label for Trasylol to include a specific statement in the WARNING section of the label that use of Trasylol creates an increased risk of rental dysfunction and renal failure.

32. Bayer Corporation admits that the prescribing information accompanying Trasylol® sold in the United States was revised in December 2006 and now includes the statement: "Trasylol® administration increases the risk for renal dysfunction and may increase the need for dialysis in the perioperative period." Bayer Corporation denies the allegations in paragraph 32 of the Complaint to the extent they are inconsistent with the contents of the FDA-approved labeling, and denies the remaining allegations in paragraph 32 of the Complaint.

33. On or about October 27, 2003, Plaintiff's decedent Mary V. Durkin was administered Trasylol during the course of a cardiac surgery procedure performed at Advocate Christ Medical Center.

33. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 33 of the Complaint.

34. With no contributory negligence on her part, Ms. Durkin was administered Trasylol, a pharmaceutical product designed, manufactured, promoted, distributed and sold by Defendants.

34. Paragraph 34 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies that it promoted, distributed, or sold Trasylol® at the time of the procedure alleged in the Complaint. Bayer Corporation denies that it designed or manufactured Trasylol® and is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 34 of the Complaint.

35. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Ms. Durkin began experiencing renal insufficiency soon after heart surgery and subsequently went into renal failure, all of which ultimately led to her untimely death on November 23, 2003. At no time did Ms. Durkin have any knowledge that her aforementioned injuries might be related to or caused by Trasylol, nor did she have any reason to suspect that those problems might in any way be related to or caused by her physicians' perioperative use of Trasylol.

35. Paragraph 35 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the medical condition or state of mind of Plaintiff's decedent and denies the remaining allegations in paragraph 35 of the Complaint.

36. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Ms. Durkin developed kidney failure and other life threatening conditions, all of which resulted in her untimely death on November 23, 2003.

36. Paragraph 36 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the medical

condition of Plaintiff's decedent and denies the remaining allegations in paragraph 36 of the Complaint.

37. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Ms. Durkin sustained permanent and devastating injuries and ultimately, death, all with the concomitant severe pain and suffering. All of said injuries caused Mary K. Durkin extensive anxiety, distress, fear, pain, suffering, and depression, while they have substantially reduced Ms. Durkin's ability to enjoy life.

37. Paragraph 37 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the medical condition of Plaintiff's decedent, denies any liability for the injuries alleged in the Complaint, and denies the remaining allegations in paragraph 37 of the Complaint.

38. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendant, as described herein, Thomas W. Durkin as Mary V. Durkin's surviving son and Special Administrator of her estate, incurred expenses of hospital care, medical care, nursing services, medicines, x-rays and funeral and burial expenses on behalf of Mary V. Durkin.

38. Paragraph 38 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding expenses associated with the medical treatment and death of Plaintiff's decedent. Bayer Corporation denies liability for any losses or damages alleged in the Complaint and denies the remaining allegations in paragraph 38 of the Complaint.

39. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, Mary W. Durkin's capacity to earn wages was permanently destroyed.

39. Paragraph 39 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies the allegations in paragraph 39 of the Complaint.

40. As a direct, proximate and legal result of the negligence, carelessness and other wrongdoing of the Defendants, Mary W. Durkin's ability to carry out and enjoy life's activities was permanently destroyed.

40. Paragraph 40 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies the allegations in paragraph 40 of the Complaint.

41. Plaintiff hereby adopts and incorporates by reference all of the above allegations and further states as follows:

41. Bayer Corporation incorporates by reference its responses to each and every paragraph of the Complaint.

42. Defendants are liable to Plaintiff for innocent, negligent and/or willful failure to provide adequate warnings regarding the appropriate use of Trasylol to the Plaintiff's decedent and to the health care providers that prescribed Trasylol.

42. Bayer Corporation denies the allegations in paragraph 42 of the Complaint.

43. Trasylol is unreasonably dangerous, even when used for its intended purpose.

43. Bayer Corporation denies the allegations in paragraph 43 of the Complaint.

44. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants had knowledge of the dangerous risks of Trasylol.

44. Paragraph 44 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies the allegations in paragraph 44 of the Complaint.

45. Plaintiff's decedent did not have the same knowledge as Defendants and Defendants provided no adequate warning to them or to the decedent's physicians about the characteristic dangers of Trasylol.

45. Bayer Corporation denies that the warnings regarding Trasylol® were inadequate, is without knowledge or information sufficient to form a belief as to the truth of the allegation in paragraph 45 regarding the state of knowledge of Plaintiff's decedent, and denies the remaining allegations in paragraph 45 of the Complaint.

46. Defendants had a continuing duty to warn consumers and physicians, including Plaintiff's decedent, and decedent's physicians, of the risks and dangers associated with Trasylol.

46. Paragraph 46 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies that its duties are accurately stated, denies that it had any duty to provide warnings directly to Plaintiff's decedent, denies that it breached any applicable duty of care relating to Plaintiff's claims, and denies liability for any injury alleged in the Complaint.

47. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, namely Trasylol, to health care providers who were empowered to prescribe and dispense Trasylol to consumers, including Plaintiff's decedent ,without adequate warnings and Defendants misled the medical community about the risk/benefit balance of Trasylol, all of which resulted in injury to Plaintiff's decedent.

47. Bayer Corporation denies the allegations in paragraph 47 of the Complaint.

48. Despite the fact that Defendants knew or should have known that Trasylol caused unreasonable and dangerous side effects that many users would be unable to avoid by any means, they continued to promote and market Trasylol when there existed safer and more effective alternative drug products.

48. Bayer Corporation denies the allegations in paragraph 48 of the Complaint.

49. Defendants knew or should have known that consumers, and Plaintiff's decedent specifically, would foreseeably and needlessly suffer severe personal injury as a result of these Defendants' failure to warn.

49. Bayer Corporation denies the allegations in paragraph 49 of the Complaint.

50. Defendants failed to provide timely and adequate warnings to physicians, distributors, and consumers, including Plaintiff's decedent and decedent's physicians, in the following ways:

a) Failed to include adequate warnings with the medications that would alert Plaintiff's decedent and her surgeons to the dangerous risks of Trasylol.

b) Failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, kidney failure;

c) Continued to aggressively promote Trasylol, even after it knew or should have known of the risks of injury from this drug.

50. Bayer Corporation denies the allegations in paragraph 50 of the Complaint, including all subparts thereof.

51. By failing to warn Plaintiff's decedent and her physicians of the adverse health risks associated with the administration of Trasylol, Defendants breached their duty of reasonable care and safety.

51. Bayer Corporation denies the allegations in paragraph 51 of the Complaint.

52. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiff's decedent and the public.

52. Bayer Corporation denies the allegations in paragraph 52 of the Complaint.

53. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff's decedent suffered the injuries and damages set forth in this Complaint.

53. Bayer Corporation denies the allegations in paragraph 53 of the Complaint.

54. Defendants are liable to Plaintiff for the injuries and damages due to the defective design or formulation of Trasylol.

54. Bayer Corporation denies the allegations in paragraph 54 of the Complaint.

55. At all times material to this lawsuit, Defendants manufactured Trasylol.

55. Bayer Corporation denies the allegations in paragraph 55 of the Complaint.

56. At all times material to this lawsuit, Defendants were engaged in the business of distributing and selling Trasylol.

56. Bayer Corporation is without knowledge or information sufficient to form a belief as to the time frame to which paragraph 56 of the Complaint refers, but denies that it was

distributing or selling Trasylol® at the time of the procedure alleged in the Complaint. Bayer Corporation denies the remaining allegations in paragraph 56 of the Complaint.

57. Defendants sold Trasylol, which was administered to Plaintiff's decedent prior to, during, or following her heart surgery, as alleged in this Complaint.

57. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 57 of the Complaint, except that Bayer Corporation denies that it sold Trasylol® at the time of the procedure alleged in the Complaint.

58. The Trasylol administered to Plaintiff's decedent was defective in design or formulation in that when it left the hands of the Defendants, this drug was dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff's decedent, and any benefit of this drug was far outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendants intended.

58. Bayer Corporation denies the allegations in paragraph 58 of the Complaint.

59. The Trasylol administered to Plaintiff's decedent was defective due to inadequate warning(s), inadequate public or regulatory reporting regarding the results of any testing and studies, and misleading or false promotional, medical, and scientific statements.

59. Bayer Corporation denies the allegations in paragraph 59 of the Complaint.

60. On information and belief, the Trasylol administered to Plaintiff's decedent was defective due to improper manufacture in that substantial amounts of Trasylol were contaminated with foreign matter and particulate.

60. Bayer Corporation denies the allegations in paragraph 60 of the Complaint.

61. The Trasylol administered to Plaintiff's decedent was defective at the time it was distributed by the Defendants or left their control.

61. Bayer Corporation denies the allegations in paragraph 61 of the Complaint.

62. The Trasylol administered to Plaintiff's decedent was expected to reach the user without substantial change in the condition in which it was sold.

62. Bayer Corporation admits that Trasylol® is intended to be administered to patients by physicians in accordance with FDA-approved labeling and without substantial

change from the condition in which it was sold. Bayer Corporation is without knowledge or information sufficient to form a belief as to whether Trasylol® was administered to Plaintiff's decedent and, if so, whether it reached Plaintiff's decedent without substantial change from the condition in which it was sold.

63. The Trasylol administered to Plaintiff's decedent reached her without substantial change in the condition in which it was sold.

63. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 63 of the Complaint.

64. Plaintiff's decedent was a person who would reasonably be expected to use Trasylol.

64. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 64 of the Complaint.

65. The defects in the Trasylol administered to Plaintiff's decedent were a direct and proximate cause of the injuries and damages sustained by Plaintiff's decedent as set forth in this Complaint.

65. Bayer Corporation denies the allegations in paragraph 65 of the Complaint.

66. Defendants are liable to Plaintiff for the negligent development, study, manufacture, distribution and sale of the unreasonably dangerous product Trasylol.

66. Bayer Corporation denies the allegations in paragraph 66 of the Complaint.

67. At all times relevant to this lawsuit, Defendants owed a duty to consumers, including Plaintiff's decedent, and to the[i]r health care providers to assess, manage and communicate the risks, dangers, and adverse effects of Trasylol and to suspend distribution and sale of Trasylol when Defendants discovered it to be unreasonably dangerous.

67. Paragraph 67 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies liability for any injury alleged in the Complaint, denies that its duties are accurately stated, denies that it

breached any applicable duty of care relating to Plaintiff's claims, and denies the remaining allegations in paragraph 67 of the Complaint.

68. Defendants' duties included, but were not limited to, carefully and properly designing, testing, manufacturing, licensing, packaging, promoting, advertising, selling, and/or distributing Trasylol into the stream of commerce, and providing warnings with regard to this drug.

68. Paragraph 68 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies liability for any injury alleged in the Complaint, denies that the warnings for Trasylol® were inadequate, denies that its duties are accurately stated, and denies that it breached any applicable duty of care relating to Plaintiff's claims.

69. Defendants negligently and carelessly breached the above-described duties to Plaintiff's decedent by committing negligent acts and/or omissions including, but not limited to, the following:

a) Defendants failed to use ordinary care in designing, testing, and manufacturing Trasylol so as to avoid the high risk to users of unreasonable, dangerous side-effects, some of which are fatal, such as renal failure.

b) Defendants failed to accompany Trasylol with adequate warnings that would alert doctors, consumers, and other users to the potential adverse side effects associated with the use of these drugs and the nature, severity and duration of such adverse effects;

c) Defendants failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety and side effects of Trasylol.

d) Defendants failed to warn Plaintiff's decedent prior to actively encouraging the sale of Trasylol, either directly or indirectly, orally or in writing, about the possibility of becoming disabled as a result of the use of these drugs;

e) Defendants continued to promote the safety of Trasylol, while downplaying any risks, even after Defendants knew of the risk of renal failure; and

f) Defendants were otherwise careless or negligent.

69. Bayer Corporation denies the allegations in paragraph 69 of the Complaint, including all subparts thereof.

70. Although Defendants knew or should have known that Trasylol caused unreasonably dangerous side effects that many users would be unable to remedy by any means, Defendants continued to market this drug to doctors for use in cardiac surgeries, despite the fact that there were safer and less expensive alternatives available.

70. Bayer Corporation denies the allegations in paragraph 70 of the Complaint.

71. Defendants knew or should have known that consumers, like Plaintiff's decedent, would suffer injury as a result of Defendants' failure to exercise ordinary care, as described above.

71. Bayer Corporation denies the allegations in paragraph 71 of the Complaint.

72. As a direct and proximate cause of Defendants' negligent acts and/or omissions, Plaintiff's decedent suffered each of the injuries and damages set forth in this Complaint..

72. Bayer Corporation denies the allegations in paragraph 72 of the Complaint.

73. Defendants are liable to Plaintiff and Plaintiff's decedent for innocent, negligent and/or willful misrepresentations regarding the safety, efficacy, and risk/benefit ratio of Trasylol to Plaintiff's decedent and to the health care providers that prescribed, recommended, ordered, and dispensed Trasylol.

73. Bayer Corporation denies the allegations in paragraph 73 of the Complaint.

74. Through their actions and omissions in advertising, promoting, reporting to the FDA, labeling, and otherwise, Defendants fraudulently, intentionally and/or negligently made public misrepresentations of material facts to, and/or concealed material facts from physicians, the FDA, and consumers like Plaintiff's decedent, concerning the character and safety of Trasylol.

74. Bayer Corporation denies the allegations in paragraph 74 of the Complaint.

75. Those public misrepresentations and omissions include, but are not limited to, those set forth in the general allegations section of this Complaint. Those misrepresentations and omissions further include, but are not limited to, the following:

a) Defendants failed to disclose that sufficient pre-clinical and clinical testing and adequate post-marketing surveillance to determine the safety and side effects of Trasylol;

b) Defendants failed to timely disclose, and/or intentionally concealed, the interim and final results of the Walker Study showing that Trasylol use dramatically increased the risk for renal failure;

c) Defendants failed to include adequate warnings with Trasylol about the potential and actual risks, and nature, scope, severity, and duration of any serious side effects of this drug, including without limitation, the risk of renal failure; and

d) Defendants concealed and continue to conceal past and present facts – including that as early as the mid-nineties Defendants were aware of and concealed their knowledge of an association between the use of Trasylol and the dangerous side effects, including renal failure – from the consuming public, including Plaintiff's decedent, when it had a duty to disclose.

75. Bayer Corporation denies the allegations in paragraph 75 of the Complaint, including all subparts thereof.

76. Defendant's above described acts and/or omissions were performed willfully, intentionally, and with reckless disregard for the safety of Plaintiff and Plaintiff's decedent and the public

76. Bayer Corporation denies the allegations in paragraph 76 of the Complaint.

77. Defendants knew or should have known that their representations were false and that Plaintiff's decedent and her physicians would rely on them. Defendants were obligated to disclose the foregoing risks, but failed to adequately and timely do so even after they were in possession of information concerning those risks. Defendants' representations that Trasylol was safe for its intended use were false, since this drug was, in fact, dangerous to the health of Plaintiff's decedent when used to reduce perioperative bleeding in patients undergoing cardiac surgery, and there were alternative products available that were less expensive, effective and posed less risk.

77. Bayer Corporation denies the allegations in paragraph 77 of the Complaint.

80. In the alternative, Defendants failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Trasylol and communicating that information to Plaintiff's decedent.

80. Bayer Corporation denies the allegations in paragraph 80 of the Complaint.

81. At the time of Defendants' fraudulent misrepresentations and active concealment, Plaintiff was unaware of the falsity of the foregoing representations and was similarly unaware that material facts concerning Trasylol had been concealed or omitted by the Defendants. In reliance upon Defendants' misrepresentations, Plaintiff's decedent's physicians were induced to and did order Trasylol to be administered during his (sic) heart surgery.

81. Bayer Corporation denies the allegations in paragraph 81 of the Complaint.

82. If Plaintiff's decedent had known the true facts concerning the risks of the use of Trasylol, in particular the risk of renal failure, she would have requested Trasylol not be used, and would have requested that her physicians order the use of one of the safer alternatives.

82. Bayer Corporation denies the allegations in paragraph 82 of the Complaint.

83. If Plaintiff's decedent's physicians had known the true facts concerning the risks of the use of Trasylol, in particular the risk of renal failure, the physicians would not have administered Trasylol during surgery and would have administered one of the safe alternatives

83. Bayer Corporation denies the allegations in paragraph 83 of the Complaint.

84. Plaintiff's decedent's reliance and ther (sic) physicians' reliance, on Defendants' misrepresentations was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Trasylol, while Plaintiff's decedent was not in a position to know the true facts, and because Defendants aggressively marketed the use of this drug and concomitantly downplayed the risks in its use, thereby inducing Plaintiff decedent's physicians to use these drugs in lieu of other, safer alternatives. At all times relevant hereto, Defendants' corporate officers, directors and/or managing agents knew of and ratified the acts of Defendants, as alleged herein.

84. Bayer Corporation denies the allegations in paragraph 84 of the Complaint.

85. As a direct and proximate result of Plaintiff and Plaintiff's decedent's reliance, and their physicians' reliance on Defendants' misrepresentations and concealment concerning the risks and benefits of Trasylol, Plaintiff and Plaintiff's decedent suffered – and Plaintiff Thomas W Durkin continues to suffer from the injuries and damages as set forth in this Complaint.

85. Bayer Corporation denies the allegations in paragraph 85 of the Complaint.

86. As a direct result of Defendants' fraudulent concealment of the dangers of Trasylol, and consequently, their concealment of the fact that Plaintiff had a cause of action arising from Defendants' acts and omissions as set forth herein, Plaintiff was unable to and did not discover Trasylol was a defective product until September of 2006, when Defendants' fraudulent concealment of the risks of the use of Trasylol, in particular the risk of renal failure, was brought to the attention of the FDA. Therefore, Plaintiff's causes of action shall be deemed to accrue in September of 2006 minus any tolling provisions for Plaintiff decedent's untimely death.

86. Bayer Corporation denies the allegations in paragraph 86 of the Complaint.

87. Trasylol was designed, tested, manufactured, distributed, promoted and sold by the Defendants; and was expected to, and did, reach Plaintiff's decedent without a substantial change in its condition.

87. Bayer Corporation is without knowledge or information sufficient to form a belief as to the time frame to which the allegations in paragraph 87 of the Complaint refer, but denies that it tested, distributed, promoted, or sold Trasylol® at the time of the procedure alleged in the Complaint. Bayer Corporation admits that Trasylol® is intended to be administered to patients by physicians in accordance with FDA-approved labeling and without substantial change from the condition in which it was sold. Bayer Corporation is without knowledge or information sufficient to form a belief as to whether Trasylol® was administered to Plaintiff's decedent and, if so, whether it reached Plaintiff's decedent without substantial change from the condition in which it was sold. Bayer Corporation denies the remaining allegations in paragraph 87 of the Complaint.

88. Defendants, through their advertising and promotional materials, expressly warranted that Trasylol was safe for the use for which it was intended, namely as a means to reduce perioperative bleeding in patients undergoing cardiac surgery.

88. Paragraph 88 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation admits that at the time of the procedure alleged in the Complaint Trasylol® was indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery and was safe and effective when used in accordance with FDA-approved labeling. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 88 of the Complaint.

89. Defendants breached said express warranties in that Trasylol was unsafe in light of the risk of life-threatening side effects associated with its use, including, but not limited to, renal failure.

89. Bayer Corporation denies the allegations in paragraph 89 of the Complaint.

90. Plaintiff's decedent and her physicians, relied to decedent's extreme detriment on Defendants' express warranties.

90. Bayer Corporation denies the allegations in paragraph 90 of the Complaint.

91. As a direct and proximate result of Defendants' breach of express warranties, Plaintiff's decedent 2suffered [sic] from the injuries and damages set forth in this Complaint.

91. Bayer Corporation denies the allegations in the first paragraph numbered 91 of the Complaint.

91. Trasylol was designed, tested, manufactured, distributed, promoted and sold by the Defendants' and was expected to, and did, reach Plaintiff's decedent without a substantial change in its condition.

91. Bayer Corporation is without knowledge or information sufficient to form a belief as to the time frame to which the allegations in the second paragraph numbered 91 of the Complaint refer, but denies that it tested, distributed, promoted, or sold Trasylol® at the time of the procedure alleged in the Complaint. Bayer Corporation admits that Trasylol® is intended to be administered to patients by physicians in accordance with FDA-approved labeling and without substantial change from the condition in which it was sold. Bayer Corporation is without knowledge or information sufficient to form a belief as to whether Trasylol® was administered to Plaintiff's decedent and, if so, whether it reached Plaintiff's decedent without substantial change from the condition in which it was sold. Bayer Corporation denies the remaining allegations in the second paragraph numbered 91 of the Complaint.

923. Defendants, through advertising and promotional materials, impliedly warranted that Trasylol was safe for the use for which it was intended, namely as a means to reduce perioperative bleeding in patients undergoing cardiac surgery.

923. Paragraph 923 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation admits that at the time of the procedure alleged in the Complaint Trasylol® was indicated for prophylactic use to reduce

perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery and was safe and effective when used in accordance with FDA-approved labeling. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 923 of the Complaint.

94. Defendants breached said implied warranties in that Trasylol was unsafe in light of the risk of life-threatening side effects associated with its use, including, but not limited to, renal failure.

94. Bayer Corporation denies the allegations in paragraph 94 of the Complaint.

95. Plaintiff's decedent and her physicians relied to his (sic) detriment on Defendants' implied warranties.

95. Bayer Corporation denies the allegations in paragraph 95 of the Complaint.

96. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff's decedent suffered from the injuries and damages set forth in this Complaint.

96. Bayer Corporation denies the allegations in paragraph 96 of the Complaint.

97. Defendants are liable to Plaintiff Wholly (sic) separate and apart from the personal injuries sustained by Plaintiff's decedent, Plaintiff further suffered financial injury, as described below.

97. Bayer Corporation denies the allegations in paragraph 97 of the Complaint.

98. Defendants financed, assisted, supported and participated in the promotion and use of Trasylol in order to create and increase consumer demand for the drug and to increase the likelihood that physicians would order the use of Trasylol rather than other safer alternative treatments for their patients.

98. Bayer Corporation denies the allegations in paragraph 98 of the Complaint.

99. Defendants deliberately misrepresented the safety of Trasylol and intentionally concealed the risks attendant to use of the drug. In so doing, Defendants intended to and did affect the decisions of consumers and their health care providers to purchase, prescribe and use Trasylol despite the existence of substantially cheaper alternative drugs.

99. Bayer Corporation denies the allegations in paragraph 99 of the Complaint.

100. Defendants, while engaged in the conduct and practices identified above, committed one or more violations, including, but not limited to, the following:

a) Defendants made false and misleading representations and omissions of material facts regarding Trasylol;

b) Defendants concealed and otherwise failed to publicize the risks and injuries associated with Trasylol in order to promote sales of the drug and maximize profits; and

c) Defendants engaged in advertising and promotion of Trasylol without conducting sufficient pre-clinical and clinical testing and adequate post-marketing surveillance to determine the safety and side effects of Trasylol.

100. Bayer Corporation denies the allegations in paragraph 100 of the Complaint, including all subparts thereof.

101. Defendants thereby intended to and did affect the price of Trasylol, unfairly and deceptively maintaining the price of Trasylol at an inflated level not otherwise obtainable and caused Plaintiff's decedent and the consuming public generally to pay more for the drug than was warranted or than they would otherwise have paid in the absence of Defendants' misrepresentations and concealment.

101. Bayer Corporation denies the allegations in paragraph 101 of the Complaint.

102. The above-described conduct, practices, acts and omissions were immoral, oppressive, unethical and/or unscrupulous, in violation of international treaty and law, and/or offend public policy.

102. Bayer Corporation denies the allegations in paragraph 102 of the Complaint.

103. The above-described conduct, practices, acts and omissions caused consumers permanent and substantial financial loss, which loss could not reasonably have been avoided, and which was not outweighed by any countervailing benefit to the consuming public. Consumers in general , and Plaintiff's decedent in particular, incurred unnecessary expenses for a product that was purchased only because of the unfair, unscrupulous, oppressive and/or deceptive acts or practices of the Defendants.

103. Bayer Corporation denies the allegations in paragraph 103 of the Complaint.

104. As a consequence of Defendants' wrongful conduct, Plaintiff suffered an ascertainable financial loss, the difference between the price paid for Trasylol as a result of Defendants' unfair trade practices and the cost of any of the substantially cheaper, and safer, drug alternatives.

104. Bayer Corporation denies the allegations in paragraph 104 of the Complaint.

105. In addition, as a consequent of Defendants' wrongful conduct, Plaintiff suffered further ascertainable financial loss, the difference between the cost of an uneventful post-operative recovery and the additional costs for medical and hospital care and post-mortem costs (funeral expenses, etc.,) incurred as a result of the many diverse and severe consequential injuries suffered by Plaintiff's Decedent as a result of the defective drug, namely Trasylol, used perioperatively. Plaintiff contends that these additional costs and expenses would not have been incurred but for Defendants' unfair trade practices and their design, manufacture, distribution and marketing of a defective, unreasonably dangerous drug, namely, Trasylol.

105. Bayer Corporation denies the allegations in paragraph 105 of the Complaint.

106. Plaintiff is entitled to punitive damages because Defendants' actions were reckless and without regard for the public's safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiff's decedent, by making false representations about and concealing pertinent information regarding Trasylol. Defendants downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Trasylol, including renal failure and death, despite available information demonstrating the product was likely to cause serious and sometimes fatal side effects to its users.

106. Bayer Corporation denies the allegations in paragraph 106 of the Complaint.

107. The Defendants' conduct in designing, testing, manufacturing, promoting, advertising, selling, marketing, and distributing Trasylol, and in failing to warn Plaintiff, Plaintiff's decedent, Plaintiff's Decedent's physicians, and other members of the public of the dangers inherent in the use of Trasylol, which were well known to the Defendants, was attended by circumstances of fraud, malice, or willful and wanton conduct, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, particularly Plaintiff's decedent.

107. Bayer Corporation denies the allegations in paragraph 107 of the Complaint.

108. At all times material hereto, Defendants had a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of Trasylol.

108. Paragraph 108 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies liability for any

injury alleged in the Complaint, denies that its duties are accurately stated, and denies that it breached any applicable duty of care relating to Plaintiff's claims.

109. Defendants breached their duty and were wanton and reckless in their actions, misrepresentations, and omissions toward the public generally, Plaintiff's decedent specifically, in the following ways:

a) Upon information and belief, Defendants actually knew of Trasylol's defective nature, as set forth herein, but continued to design, manufacture, market, and sell Trasylol so as to maximize sales and profits at the expense of the health and safety of the consuming public, including Plaintiff and Plaintiff's decedent, and in conscious disregard of the foreseeable harm caused by Trasylol;

b) Defendants spent millions of dollars a year researching and developing medicines and aggressively marketing Trasylol, but devoted far less attention to conducting sufficient pre-clinical testing, clinical testing and adequate post-marketing surveillance of this drug; and

c) Defendants continued to promote the safety of Trasylol, while providing no warnings at all about the risk to consumers of death, kidney failure, congestive heart failure, and stroke associated with it, even after Defendants knew of that risk from multiple studies including the Walker Study.

109. Bayer Corporation denies the allegations in paragraph 109 of the Complaint, including all subparts thereof.

110. Defendants knew that Trasylol had unreasonably dangerous risks and caused serious side effects of which Plaintiff would not be aware. Defendants nevertheless advertised, marketed, distributed, and sold the medicine knowing that there were safer methods and products available.

110. Bayer Corporation denies the allegations in paragraph 110 of the Complaint.

111. Defendants' above-described actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff's decedent and the public.

111. Bayer Corporation denies the allegations in paragraph 111 of the Complaint.

112. One or more of the aforesaid violations by Defendants were committed by Defendants with reckless disregard for the safety of the public and of Plaintiff's decedent as a product user.

112. Bayer Corporation denies the allegations in paragraph 112 of the Complaint.

113. One or more of the aforesaid violations by Defendants were committed by Defendants willfully and deliberately, and caused substantial financial injury to the consuming public, the Plaintiff and Plaintiff's decedent.

113. Bayer Corporation denies the allegations in paragraph 113 of the Complaint.

114. As a direct and proximate result of the wanton and reckless actions and inactions of the Defendants as set forth above, Plaintiff is entitled to punitive damages.

114. Bayer Corporation denies the allegations in paragraph 114 of the Complaint.

***WHEREFORE**, Plaintiff requests that the Court grant her the following relief against Defendants, Bayer Pharmaceuticals Corporation, Bayer Healthcare, and Bayer A. G., jointly and severally, on all counts of this Complaint ....*

115. Bayer Corporation denies liability for any injury alleged in the Complaint and denies that Plaintiff is entitled to relief requested in the "Wherefore" clause following paragraph 114 of the Complaint.

116. Wherever Plaintiff has incorporated by reference prior allegations in the Complaint, Bayer Corporation incorporates by reference its responses to such allegations.

117. Bayer Corporation denies each and every allegation in the Complaint that relates or is directed to Bayer Corporation unless such allegations are expressly responded to in this Answer.

ADDITIONAL DEFENSES

Discovery and investigation may reveal that one or more of the following additional defenses should be available to Bayer Corporation in this matter. Bayer Corporation accordingly preserves the right to assert these separate and additional defenses. Upon completion of discovery, if the facts warrant, Bayer Corporation may withdraw any of these additional defenses as may be appropriate. Bayer Corporation further reserves the right to amend its answer and defenses, and to assert additional defenses and other claims, as discovery proceeds. Further answering, and by way of additional defense, Bayer Corporation states as follows:

Defense No. 1. Plaintiff's Complaint and each and every count contained therein fail to state a cause of action or claim on which relief can be granted against Bayer Corporation.

Defense No. 2. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or statutes of repose.

Defense No. 3. Plaintiff's claims are barred, in whole or in part, by laches, waiver, and/or estoppel.

Defense No. 4. Plaintiff's Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

Defense No. 5. To the extent applicable to the facts and circumstances of this case, Plaintiff is not a real party in interest and lacks capacity and/or standing to bring the claims asserted in the Complaint.

Defense No. 6. Plaintiff's Complaint fails to state a claim for fraud, misrepresentation, deceit, concealment, suppression and/or omission, and fails to allege the circumstances constituting fraud with the required particularity.

Defense No. 7. The alleged damages and injuries, if any, were the result of unavoidable circumstances that could not have been prevented by any person or entity, including Bayer Corporation.

Defense No. 8. Neither Plaintiff nor Plaintiff's decedent suffered any actual injury, loss, or damages because of the alleged use of Trasylol®.

Defense No. 9. The injuries and damages sustained by Plaintiff or Plaintiff's decedent, if any, resulted from an intervening or superseding cause and/or causes, and no act or omission on the part of Bayer Corporation was a proximate or competent producing cause of such alleged injuries or damages.

Defense No. 10. The injuries and damages sustained by Plaintiff or Plaintiff's decedent, if any, were caused, in whole or in part, by pre-existing or subsequent physical, medical, and/or physiological conditions, for which Bayer Corporation has no legal responsibility.

Defense No. 11. The acts and omissions of Plaintiff, Plaintiff's decedent, and/or other persons or entities, over whom Bayer Corporation had no supervision or control and for whose actions and omissions Bayer Corporation has no legal responsibility, caused or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrine of contributory negligence or fault and/or comparative negligence or fault. Plaintiff's recovery, if any, therefore is barred or should be reduced and/or apportioned in accordance with Illinois law or other applicable law.

Defense No. 12. To the extent that section 402A of the Restatement (Second) of Torts applies to Plaintiff's claims, Plaintiff's claims are barred pursuant to section 402A, comment k.

Defense No. 13. Plaintiff's claims are barred because Trasylol® provides net benefits for a class of patients within the meaning of Restatement (Third) of Torts section 6, comment f.

Defense No. 14. Plaintiff's claims are barred because Trasylol® was neither defective nor unreasonably dangerous in its design, manufacture, or marketing and was reasonably safe and reasonably fit for its intended use. The warnings and instructions accompanying Trasylol® at the time of the occurrence or injuries alleged by Plaintiff were legally adequate warnings and instructions.

Defense No. 15. To the extent applicable under governing law, the claims in the Complaint against Bayer Corporation are barred in whole or in part by the learned intermediary doctrine.

Defense No. 16. Bayer Corporation did not sell or distribute Trasylol® to Plaintiff or Plaintiff's decedent, and neither Plaintiff nor Plaintiff's decedent received or relied on any representations

or warranties as alleged in the Complaint. Plaintiff's claims for breach of warranty are barred by lack of privity between Plaintiff or Plaintiff's decedent on one hand and Bayer Corporation on the other.

Defense No. 17. Neither Plaintiff nor Plaintiff's decedent detrimentally relied on any labeling, warnings, or information concerning Trasylol®.

Defense No. 18. Plaintiff's claims for breach of warranty, express and implied, are barred by the applicable provisions of Illinois law and/or any other applicable law.

Defense No. 19. Plaintiff's claims for breach of warranty are barred because Plaintiff failed to give timely notice of any alleged breach of warranty.

Defense No. 20. Plaintiff's claims are barred, in whole or in part, because Bayer Corporation did not violate the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 et seq., and/or this Act is not applicable to this matter and/or to this Plaintiff.

Defense No. 21. Plaintiff cannot recover under the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 et seq., because the United States Food and Drug Administration, the regulatory body that administers federal laws regarding the marketing and labeling of drugs in the United States, specifically approved the labeling of Trasylol® and specifically authorized the marketing, distribution, and use of Trasylol® in the United States in accordance with that labeling.

Defense No. 22. Plaintiff's Complaint fails to state a claim on which relief can be granted in that the methods, standards, and techniques utilized with respect to the design, manufacture, testing, distribution, marketing, and sale of Trasylol®, including but not limited to adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art. Trasylol®, including its

labeling approved by the United States Food and Drug Administration, complied with the state of scientific and medical knowledge available at the time of its design, testing, manufacture, distribution, marketing, and sale. Plaintiff's recovery accordingly is barred.

Defense No. 23. Trasylol® complied with the applicable product safety regulations promulgated by the United States Food and Drug Administration. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, distribution, marketing, and sale of this prescription drug, and that it was neither defective nor unreasonably dangerous. Plaintiff's recovery accordingly is barred.

Defense No. 24. If Plaintiff and/or Plaintiff's decedent sustained the injuries or incurred the expenses as alleged in the Complaint, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of Trasylol®. Plaintiff's recovery accordingly is barred.

Defense No. 25. Plaintiff's claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution by reason of the federal government's regulation of the manufacturing, testing, marketing, sale and labeling of prescription drugs.

Defense No. 26. Plaintiff's claims regarding warnings and labeling are barred by the doctrine of primary jurisdiction, in that the United States Food and Drug Administration is charged under law with determining the content of warnings and labeling for prescription drugs.

Defense No. 27. Plaintiff cannot state a claim with regard to the warnings and labeling for prescription drugs because the remedy sought by Plaintiff is subject to the exclusive regulation of the United States Food and Drug Administration.

Defense No. 28. This Court should abstain from adjudicating Plaintiff's claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription

drug labeling by the United States Food and Drug Administration.

Defense No. 29. Any claims by Plaintiff relating to alleged communications with governmental regulatory agencies are barred in whole or in part under applicable law, including the First and Fourteenth Amendment rights to petition the government.

Defense No. 30. Plaintiff's claims are barred in whole or in part because the commercial speech relating to Trasylol® was not false or misleading and is protected under the First and Fourteenth Amendments to the United States Constitution and applicable state constitutional provisions.

Defense No. 31. Plaintiff's claims purportedly asserted under statutes and regulations relating to prescription drugs fail, in whole or in part, because those statutes and regulations do not contain or create any private cause of action.

Defense No. 32. Plaintiff's recovery of damages in this action is barred or limited by applicable wrongful death law and jurisprudence.

Defense No. 33. To the extent Plaintiff seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

Defense No. 34. To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Bayer Corporation, if any, should be reduced accordingly.

Defense No. 35. Plaintiff's Complaint fails to state a claim on which relief can be granted as to costs and disbursements, attorney fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, unjust enrichment, disgorgement, restitution, or treble damages.

Defense No. 36. Plaintiff's Complaint fails to state a claim against Bayer Corporation on which relief can be granted for punitive or exemplary damages.

Defense No. 37. Bayer Corporation denies any conduct for which punitive or exemplary damages could or should be awarded and denies that Plaintiff has produced evidence sufficient to support or sustain the imposition of punitive damages against Bayer Corporation pursuant to the applicable standards of proof.

Defense No. 38. Permitting recovery of punitive or exemplary damages in this case would be unconstitutionally vague and/or overbroad, would violate Bayer Corporation's constitutional rights as secured by the Fifth, Seventh, and Fourteenth Amendments to the United States Constitution, and would contravene the prohibition of excessive fines and other provisions of the United States Constitution, the Illinois Constitution, and any other applicable state constitution.

Defense No. 39. Plaintiff cannot recover punitive or exemplary damages against Bayer Corporation because such an award, which is penal in nature, would violate Bayer Corporation's rights under the United States Constitution, the Illinois Constitution, and any applicable state constitution, unless Bayer Corporation is afforded the same procedural safeguards as are criminal defendants.

Defense No. 40. Any imposition of punitive or exemplary damages in this case against Bayer Corporation would contravene the Commerce Clause of the United States Constitution, in that such an award would constitute an undue and unreasonable burden on interstate commerce.

Defense No. 41. With respect to Plaintiff's demand for punitive damages, Bayer Corporation incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under Illinois law or other applicable state law.

Defense No. 42. Plaintiff cannot recover punitive or exemplary damages in this action under the Illinois Wrongful Death Act, 740 ILCS 180/1, or the Illinois Survival Act, 755 ICLS 5/27-6.

Defense No. 43. No act or omission of Bayer Corporation was intentional, fraudulent, malicious, willful, wanton, reckless, in any way morally culpable, or made with conscious, malicious, or intentional disregard for the health and well-being of Plaintiff's decedent or others. Bayer Corporation asserts any statutory or judicial protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

Defense No. 44. Plaintiff's claim for punitive damages against Bayer Corporation cannot be sustained because, in all respects pertinent to this action, Bayer Corporation complied with applicable industry standards and did not engage in a deliberate course of conduct which knowingly endangered those using Trasylol®.

Defense No. 45. Plaintiff's claim for punitive damages against Bayer Corporation cannot be sustained to the extent that, prior to the entry of any judgment or award in this case, an award of punitive or exemplary damages has been recovered from Bayer Corporation in a court of this state relating to Trasylol®.

Defense No. 46. Plaintiff's Complaint seeks damages in excess of those permitted by law. Bayer Corporation asserts any statutory or judicial protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

Defense No. 47. Plaintiff's Complaint fails to state a claim on which relief can be granted for joint and several liability.

Defense No. 48. Bayer Corporation adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with Bayer Corporation's defenses pleaded in this Answer.

WHEREFORE, Bayer Corporation denies any and all liability with regard to Plaintiff's claims and respectfully requests that Plaintiff's claims against it be dismissed with prejudice and that Bayer Corporation be awarded such general, further relief as justice may require.

JURY DEMAND

Bayer Corporation respectfully requests that a jury try the issues in this matter.

December 20, 2007 Defendant Bayer Corporation

/s/ Elizabeth C. Curtin
One of Its Attorneys

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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing documents were sent by U.S. Mail, postage pre-paid and/or electronically delivered through this Court's Electronic Filing System on this 20th day of December, 2007, to the following counsel of record:

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